

**This Page Is Inserted by IFW Operations
and is not a part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

**AMENDMENT AND RESPONSE
UNDER 37 C.F.R. §1.111
08/921,533
02880/158**

the present response. Support for these amendments can be found on page 5, lines 22-23.

Claims 1 and 16 were rejected under 35 U.S.C. §112 for allegedly containing new matter. Claims 1-6 and 11-20 were rejected under 35 U.S.C. §102 as allegedly being anticipated by U.S. Patent No. 5,084,051 to Tormala et al (the '051 patent). Claims 1-8 and 11-22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '051 patent. Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '051 patent in view of the journal article "*In Vivo Evaluation of Hydroxyapatite Reinforced Polyethylene Composites*" by Bonfield ("Bonfield").

Claim Amendments Render Rejection Under 35 U.S.C. §112 Moot

Claims 1 and 16 were rejected under 35 U.S.C. §112 as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to the office action, the recitation, "the resorbable polymeric reinforcing component as a large-scale reinforcing element is mixed with the resorbable polymeric matrix component" is new matter. Without touching upon the merits of this rejection, Applicants maintain that this rejection is rendered moot in light of the present amendments to claim 1 and 16 that delete the objectionable language.

Claims 1-6 and 11-20 Are Not Anticipated by the '051 Patent

Claims 1-6 and 11-20 were rejected as allegedly being anticipated by the '051 patent. Independent claim 1 recites, *inter alia*, a biodegradable and bioactive composite material for

**AMENDMENT AND RESPONSE
UNDER 37 C.F.R. §1.111
08/921,533
02880/158**

surgical osteosynthesis applications comprising “at least one oriented resorbable polymeric reinforcing component.” Applicants submit that the ‘051 patent neither teaches nor suggests at least one oriented resorbable polymeric reinforcing component. For at least this reason, Applicants submit that claim 1 (and all claims that depend therefrom) are not anticipated by the ‘051 patent. Similarly, claim 16 recites, *inter alia*, a biodegradable and bioactive composite material for surgical osteosynthesis applications comprising “at least one oriented resorbable polymeric reinforcing component in fiber form.” Applicants submit that the ‘051 patent neither teaches nor suggests at least one oriented resorbable polymeric reinforcing component. For at least this reason, Applicants submit that claim 16 is not anticipated by the ‘051 patent.

Claims 1-8 and 11-22 and 9-10 Are Not Rendered Obvious over the ‘051 Patent

Claims 1-8 and 11-22 were rejected under 35 U.S.C. §103(a) as being obvious in view of the ‘051 patent. Applicants again submit that the ‘051 patent does not teach or suggest at least one oriented resorbable polymeric reinforcing component and there is no motivation to modify the ‘051 patent to teach or suggest at least one oriented resorbable polymeric reinforcing component. For at least this reason, Applicants submit that claim 1 (and all claims that depend therefrom) and claim 16 are not rendered obvious by the ‘051 patent.

Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being obvious over the ‘051 patent in view of Bonfield. Applicants submit that Bonfield does not teach or suggest at least one oriented resorbable polymeric reinforcing component and therefore does not overcome the deficiencies of the ‘051 patent with respect to independent claim 1, the claim from which claims

**AMENDMENT AND RESPONSE
UNDER 37 C.F.R. §1.111
08/921,533
02880/158**

9 and 10 depend. Therefore, Applicants submit that even if there were a motivation to combine the teachings of Bonfield with the '051 patent, which Applicants are in no way conceding, the combined references do not teach or suggest an oriented resorbable polymeric reinforcing component. Applicants therefore submit that claims 9 and 10 are not rendered obvious by the '051 patent in view of Bonfield.

**AMENDMENT AND RESPONSE
UNDER 37 C.F.R. §1.111
08/921,533
02880/158**

CONCLUSION

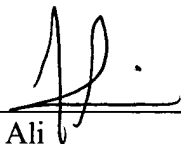
Applicants submit that the subject application is in condition for allowance, and respectfully requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicants' attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON

Date: Sept 10 2002



Zeba Ali
Reg. No. 51,392

1500 K St. Suite 700
Washington, D.C. 20005-1257
General Tel: 202-220-4200
Direct Dial: 202-220-4265
Fax: 202-220-4201

**AMENDMENT AND RESPONSE
UNDER 37 C.F.R. §1.111
08/921,533
02880/158**

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 1. (Four Times Amended) A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one oriented resorbable polymeric reinforcing component [as a large scale reinforcing element, wherein said polymeric reinforcing component is mixed with said matrix component,] and iii) at least one bioceramic or bioglass reinforcing component [as a smaller scale reinforcing element mixed with said matrix component, said bioceramic or bioglass reinforcing component being a bony ongrowth agent having coarse particles, wherein said composite material is ductile].

Claim 16. (Four Times Amended) A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one oriented resorbable polymeric reinforcing component in fiber form[, wherein said polymeric reinforcing component is mixed with said matrix component], and iii) at least one bioceramic or bioglass reinforcing component [as a bony ongrowth agent having coarse particles and] mixed with said matrix component, the diameter of the oriented resorbable polymeric reinforcing component being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component[, said composite material further having increased mechanical strength and ductility].